UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/260,536	06/16/94	LURENCE R	57704

SCHEINER, L

18N1/0803

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EXAMINER	
ART UNIT	PAPER NUMBER
1813	7

DATE MAILED: 08/03/95

NOTICE OF ABANDONMENT

This application is abandoned in view of:

1. ☑ Applicant's failure to respond to the Office letter, mailed 1/4/95.
2. ☐ Applicant's letter of express abandonment which is in compliance with 37 C.F.R. 1.138.
3. ☐ Applicant's failure to timely file the response received _____ within the period set in the Office letter.
4. ☐ Applicant's failure to pay the required issue fee within the statutory period of 3 months from the mailing date of _____ of the Notice of Allowance.
   - ☐ The issue fee was received on _____.
   - ☐ The issue fee has not been received in Allowed Files Branch as of _____.

   In accordance with 35 U.S.C. 151, and under the provisions of 37 C.F.R. 1.316(b), applicant(s) may petition the Commissioner to accept the delayed payment of the issue fee if the delay in payment was unavoidable. The petition must be accompanied by the issue fee, unless it has been previously submitted, in the amount specified by 37 C.F.R. 1.17(l), and a verified showing as to the causes of the delay.

   If applicant(s) never received the Notice of Allowance, a petition for a new Notice of Allowance and withdrawal of the holding of abandonment may be appropriate in view of Delgar Inc. v. Schuyler, 172 U.S.P.Q. 513.
5. ☐ Applicant's failure to timely correct the drawings and/or submit new or substitute formal drawings by _____ as required in the last Office action.
   - ☐ The corrected and/or substitute drawings were received on _____.
6. ☐ The reason(s) below.

LM
8/1/95

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-17 of copending application Serial No. 08/055,519. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method claims broadly drawn to "sarcoma" and "carcinoma" would encompass the more narrowly defined methods of application Serial No. 08/055,519.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide an adequate written description of the invention as now claimed.

The specification as originally filed fails to describe a "method of treating cancer". The specification fails to describe what constitutes treatment and there is no common and well-known meaning for the term "treatment". It is unclear whether this term refers to delaying or slowing down advancement of symptoms, alleviation, or reducing progression. Furthermore, the claims are unduly broad since many cancers having different etiologies are known. It appears that only solid tumors have been shown; leukemia cells appear to be unresponsive to NDV (based on the art), and metastasis has not been addressed. The results achieved in instant examples are not predictive of the effect of NDV on all cancers as claimed. Furthermore, no examples have been set forth which would support enablement of claims drawn to "in combination with another biologically or chemically active agent". That is, an immunosuppressive agent, cytotoxic, cytostatic, immunoadjuvant, cytokine, antibody or

chemotherapeutic compound has not been taught. Moreover, applicants theorize in their 1992, Journal of Surgical Research, Vol. 52, No. 5, paper that complete tumor regression results in immunodefficient mice were principally due to direct viral oncolysis, which is in contrast to other workers who have postulated a primarily immune-mediated mechanism. In short, the scope of claims 1-4 is wholly indeterminate. Instant claims read on so many combinations of cancers and agents (including inoperative combinations) that one cannot adequately determine their scope.

Claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in failing to recite proper process steps. The recitation of "administering to the mammal an effective amount of Newcastle Disease Virus" is not a proper step or series of steps. Ex parte Erlich 3 USPQ 2d 1011. Where and how and in what amount is the virus administered? Is the virus live or attenuated? Also no amounts of "agents" have been recited in the claims. It is additionally noted that based

on the art, the amount of virus to be administered may vary significantly, and toxicity of virus based on solubility parameters appears to be an important consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Bohle et al.

Claims 1-4 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Cassel et al.

Claims 1-4 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Murray et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same

person or subject to an obligation of assignment to the same person.

Claims 1-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Reichard et al.

It is noted that although Reichard et al appears in the Journal of Surgical Research in May of 1992, the paper was presented at the Annual Meeting of the Association for Academic Surgery in November of 1991.

Reichard et al teach the evaluation of direct cytolytic effects of NDV on a variety of human tumor cells, both in vitro and in vivo, and establish NDV's specificity for tumor versus normal cells. Moreover, they report that data from plaque assays, from their virus yield studies, and from their athymic animal experiments all suggest that tumor cells are susceptible to NDV replication and virus-mediated cytolysis, while normal cells are not. They clearly theorize that the selective sensitivity of tumor cells to NDV may be due to the unique presence of a viral membrane receptor or to differential uptake, replication, or release of the virus. They state that it is unlikely that the effects are due solely to selective infection of rapidly growing cells, since NDV had little effect on rapidly dividing leukemia cells. They also conclude that it is not likely that the cell of origin determines the sensitivity to NDV, since tumor lines representing three diverse classes were examined and were all susceptible to the effects of NDV. In

their plaque assay, virus is unable to diffuse in the agar so that each plaque represents the effect of one infective virus particle that has progressively replicated and lysed adjacent cells. Further, they state that the selective efficiency of NDV is additionally supported by the data from athymic animals, in which subcutaneous lesions injected simultaneously with live NDV completely regressed. Histology confirmed early cell-to-cell fusion and lysis, as demonstrated by the presence of multinucleated giant cells and of tumor cell necrosis. Complete tumor regression in these immunodeficient mice, combined with the minimal inflammatory cell infiltrate seen histologically even after 48 hours, suggest that these effects were principally due to direct viral oncolysis. Reichard et al state that this is in contrast to other workers, who have postulated a primarily immune-mediated mechanism.

In light of the findings of Reichard et al it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed NDV in a method for direct detection of cancer cells since the data clearly suggests that both viral replication and cytolysis are specific to the transformed cell, tumor, and chick embryo cell (natural host), while normal cells are not susceptible. A method of treating cancer in mammals would have also been obvious in view of their studies since NDV-tumor specificity is clearly taught. Also with

regard to a detection method, limitations drawn to imaging agents and radioisotopes represent obvious modifications related to establishing optimal reaction conditions. Such parameters in this art would be determined by routine experimentation. In re Aller et al, 105 USPQ 233 (CCPA - 1955).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner whose telephone number is (703) 308-1122.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM 1 Fax Center number is (703) 308-4227.

LAS

Laurie Scheiner/LAS
January 2, 1995

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GROUP 180